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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,223	07/14/2000	Jay A. Nadel	UCSF-085CIP	7019

7590 10/07/2003

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EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/07/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action SummaryApplication No.
09/616,223Applicant(s)
Nadel et alExaminer
Jane ZaraArt Unit
1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 22, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-9, 11-16, and 20-26 is/are pending in the application.
- 4a) Of the above, claim(s) 4-9, 11, and 20-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 12-16, and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

File

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DETAILED ACTION

This Office action is in response to the communication filed July 22, 2003, Paper No. 15.

Claims 1, 3-9, 11-16, 20-26 are pending in the instant application.

Election/Restriction

This application contains claims 4-9, 11 and 20-25, drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments and Amendments

Any rejections not repeated in this Office action are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claims 1, 3, 12-16 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Office action mailed January 2, 2002, Paper No. 9.

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Applicant's arguments filed July 22, 2003 have been fully considered but they are not persuasive. Applicants argue that adequate written description has been provided in the instant disclosure for the broad genus comprising any EGF-R antagonist that is a kinase inhibitor, and which binds to EGF-R, because a number of tyrosine kinase inhibitors have been disclosed in the specification. Applicants assert furthermore that working examples of the tyrosine kinase inhibitors BIBX1522 and AG1478 have been provided in the specification which also contribute toward providing adequate written description for this broad genus. Contrary to Applicants' assertions, the wide array of species encompassed within the claimed genus, comprising any antagonist that binds to EGF-R and inhibits tyrosine kinase, has not been adequately described in the instant disclosure. A cursory examination of EGF-R related publications within the scientific literature indicates the existence of a very wide array of compounds and reagents comprising antagonists that bind to EGF-R and inhibit tyrosine kinase. No distinguishing features concisely shared by members of this broad genus have been provided in the instant disclosure. The scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between members of the genus is permitted. Concise structural features that could distinguish structures or compounds within the genus from others is missing from the disclosure. Applicants' argument that the written description requirement only requires description of identifying characteristics is not persuasive because the complete structure of a representative number of species in addition to the species' identifying characteristics are needed. Applicants have not provided sufficient description to meet these requirements. The

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instant disclosure fails to provide a representative number of species to describe this broad genus claimed. Therefore, the rejection for lacking adequate written description is maintained.

Claims 1, 3, 12-16 and 26 are rejected under 35 U.S.C. 112, first paragraph, for lacking enablement over the scope claimed, for the reasons of record set forth in the Office action mailed January 2, 2002, Paper No. 9.

Applicant's arguments filed July 22, 2003 have been fully considered but they are not persuasive. Applicants argue that sufficient working examples have been provided for the scope of the claims, drawn to methods of reducing goblet cell hyperplasia in an airway of an individual comprising the administration of any and/or all antagonists of epidermal growth factor receptor (EGF-R) that binds to the EGF-R. The examples provided in the instant specification, including examples 1, 2 and 3, teach the reduction in airway mucus hypersecretion in animal models comprising the intratracheal instillation or the intraperitoneal administration of the tyrosine kinase inhibitor BIBX1522. The specification also teaches the reduction of mucus (MUC5) expression in target cells in vitro following the administration of BIBX1522 or tyrphostin AG129. No examples have been provided, however, for the reduction of goblet cell hyperplasia or the treatment of nasal polyps in any and/or all individual organisms comprising the administration, by any route, of any and/or all EGF-R antagonists that bind EGF-R. A representative number of the various members of this very broad genus, comprising any EGF-R antagonist that binds to EGF-R, and which is a tyrosine kinase inhibitor, has not been shown to be effectively delivered to the appropriate target cells in the airways of any organism whereby airway goblet cell hyperplasia has

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been reduced or nasal polyps have been treated. The examples provided of the in vitro administration of BIBX1522 or of AG129, or of the intratracheal instillation or intraperitoneal (pre)administration of the known inhibitor, BIBX1522, or the antagonism of EGF-R by anti-TGF-alpha antibody, are not representative of the successful delivery to the appropriate target cells in the airway of individuals comprising the administration, via any route, of any antagonist of EGF-R which binds to EGF-R in an organism and which is tyrosine kinase inhibitor, whereby airway goblet cell hyperplasia has been reduced, or whereby nasal polyps have been treated..

Conclusion


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

JZ

October 3, 2003